REMARKS

Upon entry of this amendment, claims 1-3, 6-8, 11-19, 22-30, and 33-43 are pending in the instant application. Claims 4-5, 9-10,20-21, 31-32 and 44-45 have been cancelled without prejudice or disclaimer. Applicants reserve the right to prosecute the cancelled subject matter as well as the originally filed claims in later continuing applications. Claims 1, 6, 17, 28 and 39 have been amended. The present amendments are fully supported by the specification and the claims as originally filed. For example, support for the cell populations recited by amended claim 1 is found at least in Example 11, 16-20, and 23-25. Support for the FGF-CX and FCTRX amino acid sequences recited by amended claims 1, 6, 17, 28 and 39 is found at least in Tables 1-7, while support for the deletion variants of SEQ ID NO:2 is found at least in Examples 10-11 and support for the C-terminal p35 FCTRX fragments is found at least in Example 21. Support for the gastrointestinal inflammatory pathology, as recited by amended claims 6, 17, 28 and 39 is found at least at page 3, lines 10-22. Accordingly, no new matter has been added by the amendments presented herein.

Objections to the Specification

The Examiner has objected to the specification as being informal. n particular, the Examiner has requested a new Title of the Invention that is "clearly indicative of the invention to which the claims are directed". In addition, the Examiner has requested that the priority information in the Related Applications section be updated and that all typographical errors in the specification be corrected, including the identification and capitalization of all trademark terms throughout the application.

The specification has been amended herein to include a new Title of the Invention, to correct all inadvertent typographical errors and to capitalize all trademark terms. Accordingly, withdrawal of these objections are requested.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-38 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. In particular, the Examiner has indicated that claims 1, 4-6, 9-10, 17, 20-21, 28 and 31-32 are rejected as being indefinite for reciting the terms "FGFCX, FCTRX and p35" as

"claiming biochemical molecules by a particular abbreviated name given to the protein by various workers in the field fails to distinctly claim what that protein is." (Office Action, page 4). In addition, the Examiner has stated that the term "the at least one cell" in line 2 of claim 1 lacks sufficient antecedent basis. Finally, claims 1, 6, 17, and 28 have been rejected as being incomplete for failing to refer the method steps back to the preamble and for failing to relate the method steps to the preamble.

The independent claims have been amended herein to recite specific FGF-CX and FCTRX polypeptides, as identified by sequence identifiers, and deletion variants and C-terminal fragments thereof. In addition, these claims have been amended to relate the method steps back to the preamble. As such, Applicants submit that the amended claims presented herein are clear and definite, and this rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1, 4-6, 9-10, 17, 20-21, 28 and 31-32 have been rejected under 35 U.S.C. § 112, first paragraph for lack of written description. According to the Examiner, "only the isolated polypeptide sequences of SEQ ID NO: 2, 4, 5, 8, 10, 12 and 14 but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph." (Office Action, page 7).

Independent claims 1, 6, 17 and 28 have been amended to recite methods of using compositions that include a FGF-CX polypeptide and a FCTRX polypeptide, wherein FGFCX polypeptide comprises the amino acid sequence of SEQ ID NO:2 or a deletion mutant of the amino acid sequence of SEQ ID NO:2 and said FCTRX polypeptide is selected from SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12 SEQ ID NO:14, and C-terminal fragments thereof having an apparent molecular weigh of approximately 35 kDa.

The claimed polypeptides are described throughout the specification as originally filed, *e.g.*, in Tables 1-7, in Examples 10-11 and in Example 21. Thus, the disclosure provided throughout the as-filed specification is commensurate with the scope of the amended claims presented herein.

Accordingly, Applicant submits that the specification provides sufficient written description of the claimed nucleic acid molecules so as to reasonably convey to one skilled in the

relevant art that the inventors had possession of the claimed invention at the time the instant application was filed. As such, withdrawal of this rejection is requested.

Enablement

Claims 1, 4-6, 9-10, 17, 20-21, 28 and 31-32

The Examiner has also rejected claims 1, 4-6, 9-10, 17, 20-21, 28 and 31-32 under 35 U.S.C. § 112, first paragraph for lack of enablement. In particular, the Examiner has indicated that the specification, "while being enabling for FGF-CX polypeptide with amino acid sequence of SEQ ID NO:2 and FCTRX polypeptide with amino acid sequence of SEQ ID NOs: 4, 6, 8, 10, 12 and 14, does not reasonably provide enablement for various polypeptides including FGFCX, FCTRX, "a variant of SEQ ID NO:2 wherein up to 15% of the residues provided in SEQ ID NOs: 2, 4, 6, 8, 10, 12 and 14 are changed according to a conservative amino acid substitution" or "a deletion mutation of 2, 4, 6, 8, 10, 12 and 14" or "a variant of a deletion mutant of SEQ ID NOs: 2, 4, 6, 8, 10, 12 and 14 wherein up to 15% provided in the deletion variant are changed according to a conservative amino acid substitution" or "a p35 form of a FCTRX" or "a variant of a p35 form of a FCTRX polypeptide wherein up to 15% provided in the [p35 form] are changed according to a conservative amino acid substitution". (Office Action, pages 7-8).

As described above, independent claims 1, 6, 17 and 28 have been amended to recite the use of compositions that include a FGF-CX polypeptide and a FCTRX polypeptide, wherein FGFCX polypeptide comprises the amino acid sequence of SEQ ID NO:2 or a deletion mutant of the amino acid sequence of SEQ ID NO:2 and said FCTRX polypeptide is selected from SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12 SEQ ID NO:14, and C-terminal fragments thereof having an apparent molecular weigh of approximately 35 kDa.

Applicants submit that the specification provides ample guidance so as to be enabling for the claimed FGF-CX and FCTRX polypeptides, and undue experimentation would not be required to identify which polypeptides are encompassed by the scope of the amended claims presented herein in order to practice the claimed invention. Accordingly, withdrawal of this rejection is requested.

Claims 6-38

The Examiner has also rejected claims 6-38 under 35 U.S.C. § 112, first paragraph for lack of enablement. In particular, the Examiner has indicated that the specification, "while being enabling for the method of treatment of a subject with inflammatory bowel disease, specifically Colitis and Crohn's disease by administering a composition comprising a combination FGFCX polypeptide of SEQ ID NO:2 and FCTRX of SEQ ID NO: 4 or 6, the specification does not reasonably provide enablement for the method of treatment or method of delaying the onset or a method of ameliorating a subject suffering with non gastro inflammatory pathology by administering a composition comprising combination of all FGF-CX polypeptides and all FCTRX polypeptides or variants of these polypeptides". (Office Action, page 12).

Claims 6, 17 and 28 have been amended to recite methods of treating, delaying the onset of, or ameliorating a gastrointestinal inflammatory disorder using a specific subset of FGF-CX and FCTRX polypeptides. Applicants submit that the specification provides ample guidance so as to be enabling for the claimed methods of treating, delaying or ameliorating a gastrointestinal inflammatory disorder using the claimed subset of FGF-CX and FCTRX polypeptides, and undue experimentation would not be required to practice the claimed invention. This rejection should, therefore, be withdrawn.

Claims 1-5

The Examiner has also rejected claims 1-5 under 35 U.S.C. § 112, first paragraph for lack of enablement. In particular, the Examiner has indicated that the specification, "while being enabling for the method of promoting the growth of intestinal epithelial cells, colonic cells, NIH 3T3 cells, human primary osteoblast cells and pulmonary artery smooth muscle cells by contacting the cells with a composition comprising a combination of FGFCX polypeptide of SEQ ID NO:2 and FCTRX polypeptide of SEQ ID NO:4 and 6, the specification does not reasonably provide enablement for the method of promoting the growth of a population of cells comprising contacting at least one cell with a composition, comprising a polypeptide, wherein a composition comprises a combination of all FGFCX polypeptides and all FCTRX polypeptides or the variants of these polypeptides in the instant invention". (Office Action, page 15).

Claim 1 has been amended herein to recite a method of promoting the growth of a population of cells selected from intestinal epithelial cells, colonic cells, fibroblast cells, primary

osteoblast cells and smooth muscle cells using compositions that include a FGF-CX polypeptide and a FCTRX polypeptide, wherein FGFCX polypeptide comprises the amino acid sequence of SEQ ID NO:2 or a deletion mutant of the amino acid sequence of SEQ ID NO:2 and said FCTRX polypeptide is selected from SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12 SEQ ID NO:14, and C-terminal fragments thereof having an apparent molecular weigh of approximately 35 kDa.

Applicants submit that the specification provides ample guidance so as to be enabling for the claimed method of promoting the growth of a particular subset of cell populations using the claimed FGF-CX and FCTRX polypeptides, and undue experimentation would not be required to practice the claimed invention. Accordingly, withdrawal of this rejection is requested.

Double Patenting Rejection

Claims 6-16 and 28-36 have been rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11-26 of U.S. Patent No. 6,982,250 ("the '250 patent"), and claims 1-38 have been rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6-8, 19, 21-30 and 32-38 of co-pending Application No. 10/321,962, which has been issued as U.S. Patent No. 7,189,693 ("the '693 patent").

Applicants submit herewith a terminal disclaimer over the '250 patent and the '693 patent. Accordingly, Applicants request that the Examiner withdraw this double-patenting rejection.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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